

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA**

The United States of America, *ex rel.*
Joseph M. Thomas, Bringing this Action
on Behalf of the United States of
America,

Plaintiff,

v.

Civil Action No. 1:17-cv-276-CCE-JLW

Duke University,
Duke University Health System, Inc.
William M. Foster, Ph.D., and
Erin N. Potts-Kant,

Defendants.

**RELATOR’S MEMORANDUM IN SUPPORT OF
MOTION FOR PARTIAL SUMMARY JUDGMENT—
IMPUTATION OF POTTS-KANT’S KNOWLEDGE TO DUKE**

Relator Joseph M. Thomas, by counsel, files this brief in support of his motion for partial summary judgment that the knowledge¹ of Defendant Erin N. Potts-Kant is imputed to Defendants Duke University and/or Duke University Health Systems, Inc. (“DUHS”) (collectively, “Duke”) for purposes of this FCA action.²

¹ As used herein, the term “knowledge” applies to Potts-Kant’s state-of-mind relevant to the analysis under 31 U.S.C. § 3729(b)(1).

² This motion does not address: (1) the imputation of any other individual’s knowledge to Duke; (2) the supervision (or lack thereof) of Potts-Kant, by individuals and/or Duke as an organization; or (3) whether the FCA “scienter” element has been satisfied on any particular false claim, against any particular Defendant.

I. NATURE OF THE MATTER BEFORE THE COURT

During her eight years as a Duke employee, Potts-Kant fabricated and/or falsified “nearly all” of her grant-funded flexiVent and multiplex experiments, making the results “better” in order to help Duke and its principal investigators obtain and maintain grants, and to publish scientific articles. As a result of this fraudulent course of conduct, false data was incorporated into grant applications, grant progress reports, and publications.

The FCA includes an element of scienter or state-of-mind, imposing liability for “knowing” conduct—statutorily defined to include actual knowledge, deliberate ignorance, or reckless disregard. Imputing Potts-Kant’s knowledge to Duke is proper under prevailing FCA precedent and a traditional scope of employment analysis.

Conducting flexiVent and multiplex experiments was Potts-Kant’s “[REDACTED] [REDACTED],” which W. Michael Foster (her supervisor) says he “entrusted” to her completely. This conclusion is buttressed by the contract terms by which Duke accepts grant dollars. As a condition of funding, Duke agreed to be “fully accountable” for the use of grant funds, and “responsible for the actions of its employees.” Since the fraud came to light, Duke has reaffirmed its responsibility for Potts-Kant to grant funding agencies, both in its words and actions.

Resolution of this imputation issue is appropriate now because the material facts are not in dispute, and it would streamline future summary judgment and/or trial submissions. For the reasons explained below, Relator should be granted partial

summary judgment that Potts-Kant's knowledge related to her falsifications and/or fabrications is imputed to Duke.

II. STATEMENT OF FACTS

A. Potts-Kant's employment at Duke.

Duke³ employed Potts-Kant from January 2005 to March 2013⁴ in its Pulmonary Division, where she worked under Foster's primary supervision.⁵ Foster was a senior principal investigator, who headed a "core laboratory" that performed experiments for researchers across Duke as well as externally.⁶

³ Duke admits that Potts-Kant was a Duke University employee, but denies that Potts-Kant was also a DUHS employee. D.E. 133 (Duke Ans.), ¶ 22. Duke further admits that DUHS operates the Duke University Medical Center and that certain Duke University employees share cross-appointments with DUHS. *Id.*, ¶¶ 20-22. There is conflicting evidence in the record as to whether Potts-Kant also acted on behalf of DUHS—in an employment capacity or otherwise. *See, e.g., Exhibit 1* (Potts-Kant Dep.) at 38:2-16, 748:15-749:1 (termination notice references violation of DUHS policy).

Potts-Kant deposition took place over three days—October 16-17, 2017 and July 11, 2018—and the transcript pages are consecutively numbered.

⁴ D.E. 133 (Duke Ans.), ¶ 22; **Exhibit 2** (excerpts from Dep. Ex. 96 filed under seal—Duke's June 30, 2016 Investigation Report to ORI) at 2.

⁵ D.E. 133 (Duke Ans.), ¶¶ 23-24; **Exhibit 2** at 2, 12-13, 83; **Exhibit 1** (Potts-Kant Dep.) at 21:12-21, 43:13-19, 46:19-21, 54:5-15, 56:9-24, 59:18-25, 65:12-14; **Exhibit 3** (excerpts from Dep. Ex. 427), Foster Ans. to Interrog. No. 3.

⁶ D.E. 25 (Am. Compl.), ¶ 27; D.E. 133 (Duke Ans.), ¶ 27; **Exhibit 2** at 2-3, 13-14, 83; **Exhibit 1** (Potts-Kant Dep.) at 31:6-24; **Exhibit 4** (Brass Dep.) at 218:19-220:25.

Beginning as a Research Technician II,⁷ Potts-Kant advanced at Duke,⁸ and was promoted to Clinical Research Coordinator II (“CRC II”) effective December 1, 2008.⁹

Potts-Kant’s job was 100-percent grant funded.¹⁰ Grant funding is required to do scientific research.¹¹ Duke pulmonary research scientist David Brass describes grant funding as “the current business model.”¹² But grant funding is very competitive—only about 20 percent of grant applications are successful.¹³

Scientific journal publications are tightly connected with grants, in an ongoing, cyclical way. Researchers with good publications are more likely to get grant funding—which then leads to more publications that report the work funded by a grant as “progress” under the grant.¹⁴ Former Duke principal investigator John Hollingsworth

⁷ **Exhibit 1** (Potts-Kant Dep.) at 37:7-19.

⁸ *See generally*, **Exhibit 1** (Potts-Kant Dep.) at 37-52, 63-67, 88. Potts-Kant became an exempt employee on June 1, 2006. *Id.* at 49:12-50:19.

⁹ **Exhibit 5** (Dep. Ex. 19—CRC II offer letter).

¹⁰ **Exhibit 1** (Potts-Kant Dep.) at 42:24-12, 54:23-56:8, 66:24-67:14, 174:9-175:4, 178:10-179:12; **Exhibit 6** (Dep. Ex. 18—100% Grant Funded Staff Information Form); **Exhibit 5** at 1 (“Your position . . . is paid 100% from sponsored research. This position will continue as long as we are able to provide funding.”); **Exhibit 7** (Dep. Ex. 20—8.29.12 email from Foster to Potts-Kant).

¹¹ **Exhibit 8** (Hollingsworth Dep.) at 74:1-17, 76:2-7, 79:21-80:14; **Exhibit 9** (Auten Dep.) at 30:17-19, 31:20-32:14, 51:18-24; **Exhibit 4** (Brass Dep.) at 53:23-55:25.

¹² **Exhibit 4** (Brass Dep.) at 28:6-9, 47:25-48:5, 51:4-9, 52:3-24, 54:16-21.

¹³ **Exhibit 8** (Hollingsworth Dep.) at 53:14-25; **Exhibit 9** (Auten Dep.) at 38:13-39:3; D.E. 133 (Duke Ans.), ¶¶ 2, 56.

¹⁴ **Exhibit 4** (Brass Dep.) at 51:11-53:22; **Exhibit 8** (Hollingsworth Dep.) at 63:1-66:8, 71:12-73:25; **Exhibit 9** (Auten Dep.) at 32:15-34:22; 46:15-23, 48:7-10, 49:4-51:17; **Exhibit 1** (Potts-Kant Dep.) at 119:17-122:5.

described the foundational role of publications as scientific “currency.”¹⁵ Obtaining grants and publishing papers also builds researchers’ reputation and standing, and facilitates professional advancement.¹⁶

This high-stakes environment created pressure at Duke for researchers to obtain grants and publish papers.¹⁷ Grant funding and publications were frequent topics of discussion among Duke’s principal investigators and researchers,¹⁸ because “everyone needed a grant. Everyone needed money.”¹⁹ Pulmonary Division chief Monica Kraft²⁰ emphasized the urgency of this point to a colleague at Duke in the fallout after the Potts-Kant data fraud discovery. Writing to a colleague, Kraft stated how much Duke needed the upcoming SP-A PPG renewal with NIAID:²¹ “I emphasized that this grant is our

¹⁵ **Exhibit 8** (Hollingsworth Dep.) at 35:15-40:24, 46:12-24, 73:4-11; *see also* **Exhibit 4** (Brass Dep.) at 49:10-51:3 (testifying that publications are scientists’ “product”).

¹⁶ D.E. 133 (Duke Ans.), ¶ 134 (Duke admitting that “researchers . . . can receive direct and indirect benefits from research efforts”); *id.*, ¶ 135 (Duke admitting that “for researchers, medical research can lead to promotion and advancement,” and “increase professional esteem, prestige and reputations”); **Exhibit 1** (Potts-Kant Dep.) at 122:11-123:3.

¹⁷ **Exhibit 9** (Auten Dep.) at 30:20-31:4; **Exhibit 4** (Brass Dep.) at 47:25-49:14.

¹⁸ **Exhibit 4** (Brass Dep.) at 54:6-12, 56:2-6; **Exhibit 8** (Hollingsworth Dep.) at 76:15-17; **Exhibit 9** (Auten Dep.) at 51:25-52:21; **Exhibit 1** (Potts-Kant Dep.) at 105:13-106:5, 112:12-124:7.

¹⁹ **Exhibit 1** (Potts-Kant Dep.) at 113:5-6; *see also id.* at 113:9-10 (““No grant. No job.’ [W]as my understanding.”).

²⁰ **Exhibit 8** (Hollingsworth Dep.) at 136:12-137:8.

²¹ *See generally* D.E. 186 (D.E. 190) (Thomas Decl.) ¶¶ 13-17.

shining light right now, as it's untainted and therefore we can move forward from the badness, at least in a small way"²²

During her Duke employment, Potts-Kant's "[REDACTED]

[REDACTED]"²³ Performing experiments with the flexiVent is a complicated process that is fatal for the mouse, which is anesthetized, intubated, paralyzed, and force-ventilated while the machine takes physiological measurements.²⁴ Post-mortem biological samples can then be taken as well.²⁵ The multiplex analyzes samples of biological material, identifying and quantifying specific proteins, including cytokines.²⁶ Although Foster was known as an animal physiology expert,²⁷ he had no training or experience operating either the flexiVent or the multiplex.²⁸ Instead, he "entrusted" both

²² **Exhibit 10** (Dep. Ex. 254—4.10.13 email from Kraft) (emphasis added); *see also* **Exhibit 11** (Dep. Ex. 192—4.22.13 email from Kraft to Hollingsworth) ("I also want to talk with you about our PPG – I'm worried that you won't be able to make time for it, and it's our path out of the badness.")) (emphasis added).

²³ **Exhibit 2** at 2 (emphasis added); *see also id.* at 12 (Potts-Kant was "[REDACTED]"); D.E. 25 (Am. Compl.), ¶¶ 147, 149; D.E. 133 (Duke Ans.), ¶¶ 147, 149.

²⁴ **Exhibit 12** (excerpts from Dep. Ex. 712—redacted portions filed under seal); **Exhibit 1** (Potts-Kant Dep.) at 22:24-23:7, 459:7-460:20; D.E. 25 (Am. Compl.), ¶ 148; D.E. 133 (Duke Ans.), ¶ 148; **Exhibit 2** at 2-3.

²⁵ **Exhibit 1** (Potts-Kant Dep.) at 462:11-19.

²⁶ D.E. 25 (Am. Compl.), ¶ 149; D.E. 133, Duke Ans., ¶ 149; **Exhibit 2** at 2-3; **Exhibit 1** (Potts-Kant Dep.) at 23:8-18.

²⁷ *See, e.g.,* **Exhibit 9** (Auten Dep.) at 60:4-14, 61:20-23; **Exhibit 4** (Brass Dep.) at 219:21-220:1.

machines' operation and production of data to Potts Kant.²⁹

Potts-Kant performed her experiments in an open lab space at Duke where researchers were free to observe her, even seeing the graphic real-time results of her flexiVent experiments.³⁰ The "raw machine data" from her experiments was then saved on Duke's computer network, where Duke researchers were free to review (or ask to review if outside of the Pulmonary Division) and compare it against her reported data.³¹

Potts-Kant was an important and valued member of Duke's research enterprise, treated by principal investigators more like a peer or collaborator than a technician.³² She attended conferences around the country to speak, and Foster praised her representation of Duke at these events.³³ Foster even sent her for a week-long conference in Ireland.³⁴

²⁸ **Exhibit 3**, Foster Ans. to Interrog. Nos. 4 and 5; **Exhibit 1** (Potts-Kant Dep.) at 262:24-263:11.

²⁹ **Exhibit 3**, Foster Ans. to Interrog. Nos. 4 and 5.

³⁰ **Exhibit 1** (Potts-Kant Dep.) at 265:4-266:7.

³¹ **Exhibit 1** (Potts-Kant Dep.) at 262:14-264:8, 266:10-271:13; **Exhibit 13** (Foster Dep.) at 412:6-424:7 (testifying that he understood that raw data from the flexiVent and multiplex machines was stored in nearby computers, and that there was a process involved in translating that raw machine data to the Excel spreadsheets that Potts-Kant provided); **Exhibit 3**, Foster Ans. to Interrog. No. 7; **Exhibit 2** at 14 ([REDACTED]).

³² **Exhibit 1** (Potts-Kant Dep.) at 272:23-273:5.

³³ *Id.* at 70:17-71:7.

³⁴ *Id.* at 302:19-304:17.

She consistently received excellent evaluations from Dr. Foster that highlighted her managerial roles.³⁵ She also was a co-author on at least ■ journal publications.³⁶

Foster advocated to Duke administrators for Potts-Kant's promotion, stating that she was essential to his research and grant funding.³⁷ He considered her "critical" to his research, and asserted that losing her "would cripple his research."³⁸

Foster explicitly tied Potts-Kant's importance to Duke's continued grant funding and financial success. Pointing to the recent Dean's newsletter titled "'Weathering the Storm,' *i.e.* FLAT NIH funding," Foster urged administrators to understand why he believed it "extremely important" to keep Potts-Kant at Duke. He described her as "essential personnel" to maintain his NIH grant support. And, he forecasted that losing Potts-Kant would impact "the fiscal well being of our School."³⁹

Foster reiterated Potts-Kant's importance in March 2013, even as she was placed on administrative leave due to embezzlement allegations. Foster complained to Duke administrators, summarizing Potts-Kant's numerous "commitments" and

³⁵ *Id.* at 56:9-63:9, 69:1-83:13; **Exhibit 14** (excerpts from Dep. Ex. 1—2006-07 evaluation); **Exhibit 15** (Dep. Ex. 2—2008-09 evaluation); **Exhibit 16** (Dep. Ex. 4—2009-10 evaluation); **Exhibit 17** (Dep. Ex. 5—2010-11 evaluation).

³⁶ **Exhibit 2** at 3.

³⁷ Foster wrote to Duke administrators that Potts-Kant "far exceeds many on the floor in responsibility, interaction, intellectual interests, and frees up my time and several other investigators, which permits us to spend time writing research grants and keep the research mission afloat." **Exhibit 18** (Dep. Ex. 60—December 2008 emails) at Duke-Pulm-00028356.

³⁸ *Id.* at Duke-Pulm-00028355; *see also* **Exhibit 1** (Potts Dep.) at 276:16-18.

³⁹ **Exhibit 18** at Duke-Pulm-00028354-55; *see also generally* **Exhibit 13** (Foster Dep.) at 215:7-231:23 (testimony regarding these emails).

“responsibilities” and the impact her absence would have on multiple grants, publications, and Duke scientists (listing 12 by name).⁴⁰

Hollingsworth echoed Foster’s views in March 2013, describing Potts-Kant as “an essential part of” and a “foundation to” his research program.⁴¹ Hollingsworth cited her scientific contributions to four current grants, two recent grant submissions, a recently awarded grant, and approximately 15 peer-reviewed journal publications. He protested her administrative leave, arguing that: (1) Duke would be unable to generate data necessary to defend Kraft’s SP-A PPG to the NIAID later that Spring; and (2) he would be unable to respond to reviewer concerns from a recently submitted manuscript (which would also support the SP-A PPG renewal application).⁴²

B. Potts-Kant falsified almost all of her experimental results, in order to make them better.

Potts-Kant performed “[REDACTED]” while employed at Duke.⁴³ In October 2005, however—just months after her employment began—Potts-Kant began to falsify research results.⁴⁴ After that point, she changed or made up data for “close to” or

⁴⁰ **Exhibit 19** (Dep. Ex. 460—3.6.13 Foster email) (“I can go on if you like”); *see also* **Exhibit 13** (Foster Dep.) at 234:2-235:23.

⁴¹ **Exhibit 32** (Dep. Ex. 471—March 2013 emails) at Duke-Pulm-00032386; *see also id.* at Duke-Pulm-00032384 (Potts-Kant “is so integral to our research program”).

⁴² *Id.* at Duke-Pulm-00032386.

⁴³ **Exhibit 2** at 4. Duke’s Ad Hoc Investigation Committee described its investigation as involving “[REDACTED].” *Id.* at 2; *see also id.* at 4 (an “[REDACTED]”).

⁴⁴ **Exhibit 1** (Potts-Kant Dep.) at 168:11-171:16, 181:7-11.

“nearly all” of her experiments.⁴⁵ Potts-Kant would not falsify data if it already “looked like it was supposed to” or “[w]hat it was predicted to look like.”⁴⁶ When she manipulated data, Potts-Kant “knew the altered experiment data was false.”⁴⁷

Duke drafted an admission for Potts-Kant, which she signed on April 13, 2016.⁴⁸

The admission states:

[REDACTED]

Potts-Kant testified in detail regarding her admission.⁵⁰ There, she further explained that her fake data improved the experimental results.⁵¹

Potts-Kant could make results appear better because she knew what researchers

⁴⁵ *Id.* at 186:6-25, 261:13-262:7, 360:12-15, 409:6-15, 732:18-736:9.

⁴⁶ *Id.* at 187:1-13; *see also id.* at 262:1-7, 409:6-15.

⁴⁷ D.E. 25 (Am. Compl.), ¶ 316; D.E. 135 (Potts-Kant Ans.), ¶ 316.

⁴⁸ **Exhibit 1** (Potts-Kant Dep.) at 125:16-127:17.

⁴⁹ **Exhibit 20** (Dep. Ex. 9—4.13.16 Potts-Kant declaration).

⁵⁰ **Exhibit 1** (Potts-Kant Dep.) at 125:16-148:25.

⁵¹ *Id.* at 143:6-15, 144:11-145:1; *see also id.* at 383:18-384:3; **Exhibit 4** (Brass Dep.) at 23:25-26:1 (Potts-Kant’s manipulated data “is a lie” and “not true,” and made the results better).

wanted or expected, and she was not “blinded” as to the experimental groups.⁵² The desired results were communicated to Potts-Kant in multiple ways. Researchers would tell Potts-Kant what they were looking for—informally, in a lab meeting, or over email.⁵³ Researchers would draw the desired graph on a scrap of paper.⁵⁴ Sometimes, Potts-Kant would learn that the given results were not what researchers had expected, which would allow her to then shape future results.⁵⁵

Potts-Kant’s admission was [REDACTED] to Duke’s June 30, 2016 Investigation Report to PHS’s Office of Research Integrity.⁵⁶ Duke’s Ad Hoc Investigation Committee found that Potts-Kant’s admission was “[REDACTED] [REDACTED]⁵⁷ Duke then quoted repeatedly from the admission in its Answer,⁵⁸ as what “Potts-Kant told Duke University’s Ad Hoc Investigation Committee.”⁵⁹

⁵² **Exhibit 1** (Potts-Kant Dep.) at 106:19-108:8, 119:17-21, 181:12-186:5, 320:18-21, 729:16-732:16.

⁵³ *Id.* at 182:16-20, 183:22-184:8, 184:23-185:20, 730:11-23.

⁵⁴ *Id.* at 184:9-22 (the transcript incorrectly says “grant” instead of “graph” in two places), 730:4-9.

⁵⁵ **Exhibit 1** (Potts-Kant Dep.) at 731:9-732:16.

⁵⁶ **Exhibit 2** at 9 & Appendix E (Duke-Pulm-01871807). Relator does not agree with all of the statements and conclusions in Duke’s Investigation Report.

⁵⁷ **Exhibit 2** at 11.

⁵⁸ D.E. 133 (Duke Ans.), ¶¶ 3-6, 30, 45, 154, 156-160, 212-214, 218-219, 227, 246, 316.

⁵⁹ *Id.*, ¶ 3.

C. Potts-Kant falsified results to benefit Duke and its researchers.

Potts-Kant testified that she falsified experimental results to help Duke researchers obtain and maintain grants, as well as to publish scientific articles.⁶⁰

Potts-Kant changed results to “make the PI’s happy,” and the “PI’s were happy if the results were better.”⁶¹ She knew that if grant applications exhibited more impressive results, the application was more likely to get funded.⁶² Potts-Kant falsified results, “[b]ecause researchers would be more happy if they could get a grant.”⁶³ She also understood that researchers would be more likely to keep a grant if they could report better results in progress reports, and testified that her false results could be in all types of grant submissions—such as progress reports—not just applications.⁶⁴

Likewise, Potts-Kant knew that “better results” made it more likely for researchers to get published (and published in better journals), and that publications were closely connected to grant funding.⁶⁵ Her falsifications were to designed to facilitate these processes, as she understood the importance of research results to grant funding and publications.⁶⁶

⁶⁰ **Exhibit 1** (Potts-Kant Dep.) at 143:16-147:13, 181:12-183:8, 186:6-12.

⁶¹ *Id.* at 145:7-18; *see also id.* at 273:10-18.

⁶² *Id.* at 145:19-23.

⁶³ *Id.* at 145:24-146:4.

⁶⁴ **Exhibit 1** (Potts-Kant Dep.) at 133:4-17, 146:5-9.

⁶⁵ *Id.* at 119:22-121:11, 146:10-22.

⁶⁶ *Id.* at 146:23-147:13.

Naturally, having more grants and publications also benefited Duke.⁶⁷ Duke is a prestigious university and premier research institution.⁶⁸ Medical research benefits institutions, like Duke, that conduct it.⁶⁹ Tangibly, “grants can fund certain costs of research, including salaries and institutional support and infrastructure,” and “can lead to the development of lucrative patents.”⁷⁰ Intangibly, medical research can increase an institutions’ “professional esteem, prestige, and reputations.”⁷¹

Brass explained Potts-Kant’s critical role in the scientific industry at Duke, which is fueled by grants. Speaking with Duke’s Ad Hoc Investigation Committee, Brass stated, “[i]f she keeps bringing good data, we get funded, she keeps her job, she gets a raise, everybody’s happy.”⁷²

Potts-Kant testified that she did not falsify results to help herself. Even though her job was 100-percent grant funded, Potts-Kant did not personally feel pressure to obtain grants, because—as the person running the experiments—she “figured that [she] could find a job somewhere else.”⁷³ Rather, Potts-Kant “felt the pressure” for others at Duke—

⁶⁷ **Exhibit 9** (Auten Dep.) at 53:4-54:2.

⁶⁸ D.E. 25 (Am. Compl.), ¶ 19; D.E. 133 (Duke Ans.), ¶ 19; **Exhibit 9** (Auten Dep.) at 52:22-53:3; **Exhibit 1** (Potts-Kant Dep.) at 20:21-25.

⁶⁹ D.E. 133 (Duke Ans.), ¶¶ 133-35.

⁷⁰ D.E. 133 (Duke Ans.), ¶ 134; *see also* **Exhibit 9** (Auten Dep.) at 54:3-7; **Exhibit 1** (Potts-Kant Dep.) at 148:4-9.

⁷¹ D.E. 133 (Duke Ans.), ¶ 135; *see also* **Exhibit 9** (Auten Dep.) at 53:4-54:2; **Exhibit 4** (Brass Dep.) at 56:10-57:7; **Exhibit 1** (Potts-Kant Dep.) at 148:10-25.

⁷² **Exhibit 4** (Brass Dep.) at 15:14-18:1, 20:12-19, 82:7-83:12, 258:20-260:9.

⁷³ **Exhibit 1** (Potts-Kant Dep.) at 113:11-25.

i.e., those with advanced degrees⁷⁴ pursuing careers in science—as they were “very vocal about” the pressure.⁷⁵

D. Duke agreed to be accountable and responsible for the actions of everyone involved in a grant.

Given the personal incentives and benefits inherent in grant awards (as discussed above), there is “a risk of research fraud and misconduct in connection with grant funding for medical research.”⁷⁶ Grantee institutions—like Duke University—accordingly “must exercise proper stewardship over Federal funds.”⁷⁷ Federal regulations impose an “affirmative duty to protect PHS [grant] funds from misuse by ensuring the integrity of all PHS supported work.”⁷⁸

For NIH grants,⁷⁹ the NIH Grants Policy Statement (“NIHGPS”) governs grants

⁷⁴ Potts-Kant does not have a graduate degree. **Exhibit 1** (Potts-Kant Dep.) at 17:5-20.

⁷⁵ **Exhibit 1** (Potts-Kant Dep.) at 113:14-25, 181:12-22, 182:8-14; *see also, e.g., id.* at 116:13-118:9, 316:20-318:9; **Exhibit 21** (Dep. Ex. 73—12.17.09) at Duke-Pulm-00034693 (email reacting to Potts-Kant results with the title “YeeHaa!” and stating that “This is the clincher for the paper!!!...This is the data of my career!”).

⁷⁶ D.E. 133 (Duke Ans.), ¶ 137.

⁷⁷ **Exhibit 22** (excerpts from Dep. Ex. 884—NIH Grants Policy Statement), § 8.1.1 (2012); **Exhibit 23** (Valdez Dep.) at 30:12-31:13; **Exhibit 24** (excerpts from Dep. Ex. 835—Duke’s response to 3.12.18 NIH letter) at Duke-Pulm-02028094 (“Duke University is committed to restoring the trust of the NIH in its oversight and management of NIH applications and awards”).

⁷⁸ 42 C.F.R. § 93.100(b).

⁷⁹ All but one grant at issue in this case was awarded by NIH. *See, e.g.,* D.E. 217 (Amended Exhibit C—only the first grant awarded by EPA); D.E. 25 (Am. Compl.), ¶¶ 387, 394 (Counts IV and V relate to NIH grants).

and the administration of grants,⁸⁰ and is “a term and condition of all NIH grant awards.”⁸¹ The NIHGPS includes sections addressing “Fraud, Waste and Abuse of NIH Grant Funds”⁸² and “Research Misconduct”⁸³—with the former expressly incorporating the Civil FCA as a United States remedy “relating to fraud and making false statement[s] or claims.”⁸⁴ And no NIH grant funds can be used to disseminate information that is deliberately false or misleading.⁸⁵

The NIHGPS further provides that “[t]he grantee is responsible for the actions of its employees and other research collaborators, including third parties, involved in the project.”⁸⁶ In a section titled “Legal Implications of Applications,” the NIHGPS states that the grantee representative’s signature on the grant application “certifies that the applicant organization has the ability to provide appropriate administrative and scientific oversight of the project and agrees to be fully accountable for the appropriate use of any

⁸⁰ **Exhibit 25** (Minnicozzi Dep.) at 16:20-17:12.

⁸¹ **Exhibit 26** (Dep. Ex. 799—March 12, 2018 NIH letter) at 2; *see also* <https://grants.nih.gov/policy/nihgps/index.htm> (last visited August 6, 2018) (“The NIH Grants Policy Statement (NIHGPS) makes available, in a single document, the policy requirements that serve as the terms and conditions of NIH grant awards.”).

⁸² **Exhibit 22**, § 2.3.10.

⁸³ *Id.*, § 4.1.26.

⁸⁴ *Id.*, § 2.3.10.

⁸⁵ **Exhibit 22**, § 4.2.3.

⁸⁶ *Id.*, § 4.1.26 (emphasis added).

funds awarded and for the performance of the grant-supported project or activities resulting from the application.”⁸⁷

In September 2014, Duke acknowledged its responsibilities for Potts-Kant’s actions. Duke refunded Potts-Kant’s grant-funded salary, benefits, overhead, and travel totaling almost \$740,000, informing the NIH and EPA that it was “appropriate” to do so.⁸⁸

Further, Duke recently affirmed its commitments to NIH. On March 12, 2018, NIH put Duke on special terms and conditions, due to NIH’s “concerns about Duke’s management of NIH awards.”⁸⁹ As part of the reasoning for this decision, NIH explicitly referenced this litigation.⁹⁰ Citing the NIHGPS, NIH required Duke to submit a corrective action plan by April 30, 2018.⁹¹

In Duke’s cover letter attaching its corrective action plan, Duke stated that it “is firmly committed to restoring the NIH’s trust in our institution’s research oversight process.”⁹² The corrective action plan acknowledged Duke’s role as a “steward[] of . . .

⁸⁷ *Id.*, § 2.3.6 (emphasis added); *see also id.*, § 2.1.2 (similar).

⁸⁸ **Exhibit 27** (Dep. Ex. 204—9.8.14 refund letter to NIEHS); **Exhibit 28** (Dep. Ex. 205—9.8.14 refund letter to NHLBI); **Exhibit 29** (Dep. Ex. 206—9.8.14 refund letter to EPA); **Exhibit 30** (Dep. Ex. 207—9.8.14 refund letter to NIAID); **Exhibit 31** (Dep. Ex. 208—9.8.14 refund letter to HHS Division of Payment Management enclosing check).

⁸⁹ **Exhibit 26** at 1.

⁹⁰ *Id.* (second bullet point).

⁹¹ *Id.* at 3.

⁹² **Exhibit 24** at Duke-Pulm-02028585.

sponsored program resources,”⁹³ and stated that it and the oversight programs it describes were Duke’s “highest priority.”⁹⁴ After “engaging senior leadership of the University throughout the process,” Duke reaffirmed the burdens of accepting federally-funded grant dollars: “The University accepts the responsibilities of a major research-intensive institution in the management of federal funds.”⁹⁵

III. QUESTION PRESENTED

With respect to the FCA claims brought in this case, is Potts-Kant’s knowledge related to her falsifications and/or fabrications of experimental data imputed to Duke?

IV. ARGUMENT

A. The summary judgment standard.

“Summary judgment is proper when ‘there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.’” *Rouse v. Duke Univ.*, 914 F. Supp. 2d 717, 723 (M.D.N.C. 2012) (quoting Fed. R. Civ. P. 56(a)). “The moving party has the initial burden of demonstrating the absence of any material issue of fact; once the moving party meets its initial burden, the non-moving party must come forward with evidentiary material demonstrating the existence of a genuine issue of material fact requiring a trial.” *Churchwell v. City of Concord*, No. 1:17cv299, 2018 U.S. Dist. LEXIS 98964, at *6 (M.D.N.C. June 11, 2018) (citations omitted).

⁹³ *Id.* at Duke-Pulm-02028096.

⁹⁴ *Id.* at Duke-Pulm-02028200.

⁹⁵ *Id.* (emphasis added).

B. The relevant FCA framework.

The Fourth Circuit has held that there are four distinct elements to an FCA claim: “(1) there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that involved a claim made to the government for payment.” *United States ex rel. Ahumada v. NISH*, 756 F.3d 268, 280 (4th Cir. 2014) (quotations omitted). The scienter element of “knowing” conduct is separately defined to “mean that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information.” 31 U.S.C. § 3729(b)(1)(A). No proof of a specific intent to defraud is required to show FCA “knowledge.” *Id.* § 3729(b)(1)(B). An FCA “plaintiff need not prove the defendant had a financial motive to make a false statement relating to a claim seeking government funds.” *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 921 (4th Cir. 2003) (“*Harrison II*”).

C. Potts-Kant’s knowledge is imputed to Duke because she was acting within the scope of her employment.

In FCA cases, employee knowledge is imputed to the employer when the employee acted within the scope of her employment. *See, e.g., United States ex. rel. Polukoff v. St. Mark’s Hosp.*, No. 17-4014, 2018 U.S. App. LEXIS 18539, at *31 n.9 (10th Cir. July 9, 2018) (holding that “[i]t is well established that a corporation is chargeable with the knowledge of its agents and employees acting within the scope of their authority,” and that for FCA liability, “it suffices that any employee, acting within

the scope of his or her employment, had knowledge”) (citations omitted) (emphasis in original); *United States v. Anchor Mortg. Corp.*, 711 F.3d 745, 747-78 (7th Cir. 2013) (“Corporations such as [the defendant] ‘know’ what their employees know, when the employees acquire knowledge within the scope of their employment and are in a position to do something about that knowledge.”); *accord Helton v. AT&T Inc.*, 709 F.3d 343, 356 (4th Cir. 2013) (in the ERISA context, holding that a “plan administrator can be charged with knowledge of information acquired by its employees in the scope of their employment,” after observing more generally that “courts have found that knowledge obtained by corporate employees acting within the scope of their employment is imputed to the corporation”) (quotation omitted) (citations omitted).⁹⁶

Here, Potts-Kant was acting within the scope of her employment—a concept defined by federal common law for statutes like the FCA. *Cilecek v. Inova Health Sys. Servs.*, 115 F.3d 256, 259-60 (4th Cir. 1997) (“for purpose of applying federal statutes,” and “[i]n order to establish a uniform nationwide application” of terms like “scope of employment,” courts should apply “‘the general common law of agency’ and not the law of a particular state”) (quoting in part *Community for Creative Non-Violence v. Reid*, 490

⁹⁶ In *Harrison II*, the defendant organization (Westinghouse) conceded the obvious point that “whatever knowledge its employees possessed relating to the facts of this case are imputed to it.” 352 F.3d at 920, n.11. The relevant issue was then whether the scienter element was satisfied for a false certification claim. *See, e.g., id.* at 919, n.9 (approving a jury instruction that required there be “at least one Westinghouse employee who knew of the wrongful conduct . . . that gave rise to the false statement”). At this point, Relator only seeks to establish that Potts-Kant’s knowledge is imputed to Duke, which Duke has indicated it will dispute. *See* D.E. 169 (4.27.18 Status Conference Tr.) at 36:13-15; D.E. 222 (Relator’s Notice of Dispositive Motion), ¶ 5.

U.S. 730, 740-41 (1989)) (emphasis in original). In so doing, the Fourth Circuit “has traditionally looked to sources such as the *Restatement of Agency*.” *Cilecek*, 115 F.3d at 260; accord *Garnett v. Remedi Seniorcare of Va., LLC*, 892 F.3d 140, 144 (4th Cir. 2018) (citing *Restatement (Third) of Agency Law* § 7.07 for “scope of employment”).

As defined in the Restatement:

An employee acts within the scope of employment when performing work assigned by the employer or engaging in a course of conduct subject to the employer’s control. An employee’s act is not within the scope of employment when it occurs within an independent course of conduct not intended by the employee to serve any purpose of the employer.

Restatement (Third) of Agency Law, § 7.07(2) (emphasis added).

Applying the undisputed facts in this case, Duke hired Potts-Kant and assigned her the work of flexiVent and multiplex experiments as her “[REDACTED]” during her employment. Potts-Kant’s activities in conducting and reporting flexiVent and multiplex experiments in Duke’s core laboratory were subject to Duke’s control. Foster—her direct supervisor—states that he “entrusted” her with the operation of the flexiVent and multiplex machines and the generation of experimental data. Potts-Kant performed the experiments in Duke facilities that were open to Foster and other researchers, who could observe her work and had access to the raw machine data that was electronically stored on the Duke computer system.⁹⁷

⁹⁷ See *supra* at II(A).

Potts-Kant's testimony also establishes that she did not act solely for her own purpose. Rather, she testified that the flexiVent and multiplex data falsifications were not to benefit her, but Duke—to make it more likely that Duke and its principal investigators and researchers would obtain and maintain grants, and become published in scientific journals.⁹⁸

Accordingly, Potts-Kant's knowledge related to her falsified and/or fabricated data is imputed to Duke for purposes of analyzing liability under the FCA.

D. Duke agreed to be accountable and responsible not just for Potts-Kant's knowledge, but for her actions.

Duke's federal grant awards incorporate and are subject to terms and conditions. Grant funding agencies (and institutions like Duke) recognize the risk that research misconduct and fraud, waste, and abuse of grant funds can occur, and that these wrongful actions are not necessarily sanctioned by the grantee institution. Among the United States' remedies are FCA actions.⁹⁹

Before receiving grant funds, Duke certified that it had “the ability to provide appropriate administrative and scientific oversight of the project and agrees to be fully accountable for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from the application.”¹⁰⁰ Duke also agreed

⁹⁸ See *supra* at II(B) & (C).

⁹⁹ See *supra* at II(D).

¹⁰⁰ **Exhibit 22**, § 2.3.6.

to be “responsible for the actions of its employees ... involved in the project.”¹⁰¹ In other words, the risk of grant-related fraud is contemplated by the federal grant system, and Duke accepted responsibility for that risk.

Duke has acknowledged and reaffirmed its responsibility for Potts-Kant’s grant-related actions since her fraud came to light in March 2013. In September 2014, Duke determined that it was “appropriate” to refund almost \$740,000 of grant reimbursements to NIH and EPA.¹⁰²

This past March, NIH put Duke on special terms due to concerns over Duke’s grant oversight—which include concerns related to Potts-Kant and this litigation. In its April 2018 response to NIH, Duke acknowledged that it was a “steward” of grant funds. And after close consultation with senior leadership, Duke stated that the “University accepts the responsibilities of a major research-intensive institution in the management of federal funds.”¹⁰³

Given these obligations and commitments, Duke cannot reasonably dispute its responsibility for Potts-Kant’s FCA knowledge in connection with grant-funded research.¹⁰⁴

¹⁰¹ *Id.*, § 4.1.26.

¹⁰² *See supra* at II(D).

¹⁰³ **Exhibit 24.**

¹⁰⁴ In *Harrison II*, the Fourth Circuit stated that the imputation of an employee’s knowledge of wrongdoing was “particularly appropriate,” given the organization’s related contractual obligations. 352 F.3d at 920, n.11.

V. CONCLUSION

For the foregoing reasons, the Court should grant Thomas's motion for partial summary judgment that Potts-Kant's knowledge is imputed to Duke.

This the 7th day of August, 2018.

Respectfully submitted,

JOSEPH M. THOMAS

/s/ Michael J. Finney

Matthew W. Broughton (admitted *pro hac vice*)

J. Scott Sexton (admitted *pro hac vice*)

Gregory J. Haley (admitted *pro hac vice*)

John R. Thomas, Jr. (admitted *pro hac vice*)

Michael J. Finney (admitted *pro hac vice*)

Daniel R. Sullivan (admitted *pro hac vice*)

Andrew M. Bowman (admitted *pro hac vice*)

GENTRY LOCKE

900 SunTrust Plaza

P.O. Box 40013

Roanoke, Virginia 24022-0013

(540) 983-9300

(540)983-9400 (fax)

broughton@gentrylocke.com

sexton@gentrylocke.com

haley@gentrylocke.com

jthomas@gentrylocke.com

finney@gentrylocke.com

sullivan@gentrylocke.com

bowman@gentrylocke.com

/s/ D.J. O'Brien III

D.J. O'Brien III

N.C. State Bar No. 35481

Daniel F.E. Smith

N.C. State Bar No. 41601

BROOKS, PIERCE, MCLENDON,
HUMPHREY & LEONARD, LLP
2000 Renaissance Plaza
230 North Elm Street
Greensboro, North Carolina, 27401
Tel. (336) 373-8850
Fax (336) 378-1001
dobrien@brookspierce.com
dsmith@brookspierce.com

Attorneys for Relator Joseph M. Thomas

CERTIFICATE OF WORD COUNT

I hereby certify that, pursuant to Local Civil Rule 7.3(d)(1) that the foregoing brief—exclusive of the caption, signature lines, and certificates—has 5,453 words and complies with Rule 7.3(d).

/s/ D.J. O'Brien III

D.J. O'Brien III

CERTIFICATE OF SERVICE

I hereby certify that on August 7, 2018, a true and correct copy of the foregoing was filed electronically with the Clerk of the Court using the CM/ECF system, which will send a Notice of Electronic Filing to counsel of record in this matter.

/s/ D.J. O'Brien III

D.J. O'Brien III